



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0660; FRL-9980-01-OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances” (EPA ICR Number 1188.13, OMB Control Number 2070-0038) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request that will rename and consolidate two currently approved collections under OMB Control No. 2070-0038. Public comments were previously requested on a new consolidated ICR identified as EPA ICR No. 2702.01 via the ***Federal Register*** on December 27, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: **Additional** comments may be submitted on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE ***Federal Register***].

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA-HQ-OPPT-2021-0660, online using <https://www.regulations.gov> (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public

docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Regulatory Support Branch (7101M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 566-1204; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the docket for this ICR. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's dockets, visit <https://www.epa.gov/dockets>.

Abstract: This information collection request consolidates the reporting and recordkeeping requirements associated with the premanufacture review of new chemical substances and those associated with new and existing chemical substances that are subject to significant new use rules, which are programs administered by EPA under section 5 of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2604). Originally identified as a new ICR and assigned EPA ICR No. 2702.01 (OMB Control No. 2070-NEW), this request consolidates two currently approved collections identified as EPA ICR No. 0574.18 (OMB Control No. 2070-0012) and EPA ICR No. 1188.12 (OMB Control No. 2070-0038). Based on discussions with OMB, EPA subsequently determined that the consolidated ICR should be submitted as a revision to the existing ICR approved under

OMB Control No. 2070-0038. The consolidation ICR is now identified as EPA ICR No. 1188.13 and includes a change in its title.

TSCA section 5 requires that any person who proposes to manufacture (which includes import) a “new chemical” (i.e., a chemical not listed on the TSCA section 8(b) Inventory) must provide a premanufacture notice (PMN), a Microbial Commercial Activity Notice (MCAN) or an exemption application to EPA at least 90 days prior to commencing manufacture of that chemical and that EPA review such notice and take action as appropriate. In addition, if EPA determines that a non-ongoing use of a new or existing chemical substance is a significant new use, EPA may promulgate a significant new use rule (SNUR) under TSCA section 5 to require any person who intends to manufacture (import) or process the chemical substance for that designated “significant new use” must first submit a significant new use notice (SNUN) to EPA at least 90 days prior to commencing the manufacture or processing of that chemical for that use, which allows EPA to review such notice and take action as appropriate. TSCA section 5 also requires EPA to make determinations before the conclusion of its 90-day review of the submitted notices regarding whether the manufacture, processing, distribution in commerce, use and/or disposal of the new chemical substances or the significant new use of the existing chemical substances may present unreasonable risk to health or the environment. EPA’s determination on a chemical substance or new use will dictate how and to what extent the chemical’s manufacture, use, processing and/or disposal may be restricted.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and regulations that interpret TSCA section 12(b) appear at 40 CFR part 707 and the associated paperwork activities and burdens are approved under OMB Control No. 2070-0030, ICR entitled “Notification of Chemical Exports - TSCA Section 12(b),” identified by EPA ICR No. 0795.16.

Form Numbers: 7710-23, 7710-25, 7710-56 and 6300-7.

Respondents/affected entities: Chemical manufacturers (defined by statute to include importers) and

processors, e.g., entities identified by the North American Industrial Classification System (NAICS) codes 325, Chemicals and Allied Products Manufacturers, and 324, Petroleum Refining.

Respondent's obligation to respond: Mandatory, 15 U.S.C 2604. 40 CFR parts 720, 721, 723 and 725.

Estimated number of respondents: 234 (total).

Frequency of response: On occasion.

Total estimated burden: 136,292 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$37,354,814 (per year), includes \$0 annualized capital or operation and maintenance costs.

Changes in the estimates: The consolidation of the currently approved ICRs is expected to result in an overall decrease of 56,001 burden hours and \$17,188,154 burden costs when compared to the total combined burden and costs that is currently approved by OMB. Discussed in more detail in the ICR, this decrease is an adjustment.

Courtney Kerwin,

Director,

Regulatory Support Division.

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